

Timothy C. Hester
Mark H. Lynch
Christopher N. Sipes
Paul W. Schmidt
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2401
(202) 662-6000

C. William Phillips
Michael C. Nicholson
COVINGTON & BURLING
1330 Avenue of the Americas
New York, New York 10019-5400
(212) 841-1000

Counsel for Purdue Defendants

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----	X	
In re:	:	
	:	
OXYCONTIN ANTITRUST LITIGATION	:	04-MDL-1603 (SHS)
	:	
This Document Relates To: All Cases	:	
-----	X	

PURDUE'S STATEMENT OF COUNSEL

Pursuant to the Court's Order No. 1 (Setting Initial Case Management Conference), dated December 14, 2005, Purdue's designated Counsel hereby submit this Statement to the Court.

I. Brief Statement of Factual and Legal Issues

Purdue obtained a series of patents related to OxyContin® (the "Purdue Patents") that have been at issue in litigation between Purdue and companies seeking to market generic controlled-release oxycodone products. OxyContin is a controlled-release pain medication approved by the United States Food and Drug Administration ("FDA") for the management of moderate to severe pain that lasts for an extended period of time. The active ingredient in OxyContin is oxycodone hydrochloride, an opioid analgesic.

In 1997, Boehringer Ingelheim, GmbH, Roxane Laboratories, Inc., and Boehringer Ingelheim Corporation (collectively, "Roxane") filed a New Drug Application ("NDA") with the FDA seeking approval of a controlled-release oxycodone product, Roxicodone™ SR. The FDA approved the NDA in 1998, and in 1999, Purdue filed a complaint in the Southern District of New York ("S.D.N.Y.") against Roxane. Purdue sought

declaratory and injunctive relief and damages, based on allegations that Roxane's research of, development of, and plans to market Roxicodone SR infringed the Purdue Patents. Roxane asserted counterclaims against Purdue, requesting a declaration that the Purdue Patents were invalid and unenforceable and that Roxane did not infringe the Purdue Patents. In 2000, this Court granted Purdue's motion for a preliminary injunction against Roxane, and the Federal Circuit affirmed that decision in 2001. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, et al.*, 98 F. Supp. 2d 362 (S.D.N.Y. 2000), *aff'd*, 237 F.3d 1359 (Fed. Cir. 2001).¹

In 2000, prior to the expiration of the Purdue Patents, Endo Pharmaceuticals Inc. announced plans to introduce a generic controlled-release oxycodone pain medication. Subsequently, Endo filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic controlled-release oxycodone product, and later amended the original ANDA to include additional strengths of that product. In response, in October 2000 and March and August 2001, Purdue filed patent enforcement suits against Endo in the S.D.N.Y. (the "Endo Patent Actions"). In each of the Endo Patent Actions, Endo raised counterclaims and affirmative defenses against Purdue, alleging that the Purdue Patents were invalid and unenforceable and that Purdue's effort to enforce the patents violated the antitrust laws. Specifically, Endo counterclaimed that the Endo Patent Actions were shams, brought in bad faith and used as an anticompetitive weapon. Both the patent and antitrust claims proceeded through nearly two years of fact and expert discovery. This Court then bifurcated and stayed the antitrust claims pending trial on Purdue's patent infringement claims and Endo's patent law defenses. The patent law issues were tried before this Court in July 2003.

In 2001 and 2002, Purdue also brought patent infringement actions against Impax Laboratories, Inc. and Teva Pharmaceuticals USA, Inc, in response to ANDAs filed by those companies with the FDA for approval of generic controlled-release oxycodone products. Both Impax and Teva filed antitrust counterclaims against Purdue. As in the Endo litigation, this Court bifurcated the counterclaims and stayed them pending resolution of the Endo Patent Actions.

On January 5, 2004, this Court ruled that Endo's generic controlled-release oxycodone product infringed the Purdue Patents, but the patents were unenforceable due to inequitable conduct before the U.S. Patent & Trademark Office ("PTO"). *Purdue Pharma, L.P. v. Endo Pharm. Inc.*, Nos. 00-CV-8029 (SHS), 01-CV-2109 (SHS), 01-CV-8177 (SHS), 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004). On June 7, 2005, the Federal Circuit affirmed. 410 F.3d 690 (Fed. Cir. 2005). Purdue filed a petition for panel rehearing and rehearing *en banc* with the Federal Circuit on June 21, 2005. The Federal Circuit directed Endo to file a response to the rehearing petition, which Endo submitted to the court on July 22, 2005. The Federal Circuit has not yet ruled on the rehearing petition.

¹ Also in 2000, in response to a Citizen's Petition by Purdue, the FDA stayed approval of Roxane's NDA covering Roxicodone, finding that Roxane had provided insufficient data to support the NDA application under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act.

Following this Court's *Endo* decision, a number of different plaintiffs filed suit against Purdue alleging that its conduct in procuring and enforcing its patents violated federal antitrust law or state law analogues. Although most of these cases were filed originally in the S.D.N.Y., many were brought in other state and federal courts across the country. For those cases filed in state court, Purdue sought removal to federal court, followed by transfer of those cases to this Court. Purdue also sought transfer of cases that were originally filed in other federal courts. Many of the complaints were transferred to this Court pursuant to 28 U.S.C. § 1404. In addition, the Judicial Panel on Multidistrict Litigation established an MDL Proceeding, *In re OxyContin Antitrust Litigation*, No. 1603, under which roughly a dozen complaints were transferred to this Court pursuant to 28 U.S.C. § 1407.

There are now 67 complaints and three counterclaims against Purdue that are pending before the Court. Some plaintiffs also brought claims against Abbott Laboratories, alleging that Abbott engaged in improper marketing practices in its promotion of OxyContin that expanded an unlawful monopoly over OxyContin. The following are the central issues raised in these cases:

- A. All complaints and counterclaims pending before this Court allege that Purdue suppressed competition through the filing of baseless patent infringement litigation against Endo and that such action violated federal antitrust law and/or state law analogues. (Some complaints make the same allegation with regard to the patent infringement litigation against Impax and Teva.) These claims present the question of whether Purdue engaged in "sham litigation" when it brought patent infringement action to enforce its OxyContin patents, which requires an analysis of whether the patent infringement litigation was (1) "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," and (2) brought subjectively in bad faith. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993).
- B. Approximately fifteen of the complaints and counterclaims before the Court assert that Purdue obtained the patents covering OxyContin through fraud before the PTO, in violation of federal and/or state antitrust law. These allegations require an analysis of whether Purdue's actions meet the standard of fraud on the PTO set forth in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). This question turns on whether Purdue engaged in "knowing and willful" fraud on the PTO, whether Purdue was "aware of the fraud" when it brought suit, and whether "but for" the fraud, the patent would not have been granted. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068-69, 1070 (Fed. Cir. 1998).
- C. In making their antitrust claims under federal and/or state law, plaintiffs define an alleged product market limited to the single product OxyContin. This raises the issue of whether plaintiffs have defined a relevant market sufficient to maintain a monopolization theory under Section 2 of the Sherman Act, 15 U.S.C. § 2, or state law analogues.
- D. Beyond the patent-based claims found in all complaints, six complaints raise

additional claims alleging that Purdue engaged in false marketing of OxyContin, leading to an improper increase of sales of OxyContin. Among other issues, these allegations raise the question of whether plaintiffs have standing to pursue false marketing claims and whether the marketing was in fact false.

II. Pending Motions

MOTION	DATE	PERTINENT CASES
Plaintiffs' Motion to Appoint Interim Class Counsel for End-Payor Plaintiffs Pursuant to Fed. R. Civ. P. 23(g) and for Consolidation	2/23/04	<i>A.F. of L-A.G.C. Building Trades Welfare Plan</i> , 04-CV-487 <i>United Food</i> , 04-CV-112 <i>Paper</i> , 04-CV-315 <i>Arkansas Carpenters'</i> , 04-CV-196 <i>Aznavorian</i> , 04-CV-154 <i>Krause</i> , 04-CV-314 <i>County of Suffolk</i> , 04-CV-651 <i>Drug Mart Tallman</i> , 04-CV-637 <i>Jaffe</i> , 04-CV-929 <i>Winthrop Univ. Hospital</i> , 04-CV-957 <i>Giwner</i> , 04-CV-607 <i>Lousiana Health Service</i> , 04-CV-1212
Plaintiffs' Motion for Entry of Case Management Order 1, Applicable to Direct Purchaser Plaintiffs	3/16/04	<i>Louisiana Wholesale</i> , 04-CV-229 <i>Rochester Drug Coop.</i> , 04-CV-327 <i>Meijer, Inc.</i> , 04-CV-494 <i>Valley Wholesale</i> , 04-CV-1014 <i>SAJ Distributors</i> , 04-CV-1354
Renewed Motion for an Order Appointing the Firm of Harke & Clasby Interim Class Counsel	8/11/04	<i>Balloveras</i> , 04-CV-4039
Motion for an Order Granting Partial Summary Judgment Against Certain Defendants for Violation of § 501.203 of the Florida Deceptive and Unfair Trade Practices Act	8/11/04	<i>Balloveras</i> , 04-CV-4039
Purdue's Motion to Stay Proceedings Pending Resolution of Patent Appeal	8/25/04	<i>Balloveras</i> , 04-CV-4039
Plaintiffs' Motions for Remand	various	<i>Ayala</i> , 04-CV-04960 <i>Burnham</i> , 04-CV-04895 <i>Burse</i> , 04-CV-04892 <i>Deutsch</i> , 05-CV-03287 <i>Friedman</i> , 04-CV-04575

		<i>Lynn</i> , 04-CV-04893 <i>May</i> , 04-CV-07119 <i>Ridgell</i> , 04-CV-07621 <i>Schooley</i> , 04-CV-04962 <i>White</i> , 04-CV-03295 <i>Woodson</i> , 04-CV-07120
Abbott's Motions to Dismiss	various	<i>Arkansas Carpenters'</i> , 04-CV-196 <i>Balloveras</i> , 04-CV-4039 <i>Chaballa</i> , 05-CV-3500 <i>City of NY</i> , 04-CV-3499 <i>Deutsch</i> , 05-CV-3287 <i>Kooman</i> , 04-CV-5450 <i>Lemaster</i> , 04-CV-5256 <i>Lissy</i> , 04-CV-2378 <i>Local 1199</i> , 04-CV-3093 <i>Louisiana Health Service</i> , 04-CV-1212 <i>May</i> , 04-CV-7119 <i>Painters District</i> , 04-CV-2078 <i>Paper</i> , 04-CV-315 <i>Pressley</i> , 04-CV-7115 <i>County of Suffolk</i> , 04-CV-651 <i>United Fed'n of Teachers</i> , 04-CV-1808 <i>Vista Healthplan</i> , 04-CV-2179 <i>Whittle</i> , 04-CV-2089 <i>Williams</i> , 04-CV-7080

III. Related Cases

The following cases, all pending before this Court, are related to *In Re OxyContin Antitrust Litigation*, but were not included in Attachment A to Order No. 1:

CASE NAME	DOCKET NUMBER
<i>Purdue Pharma, L.P. v. Endo Pharmaceuticals Inc.</i>	00-CV-8029 01-CV-2109 01-CV-8177
<i>Deutsch v. Purdue Pharma Co., et al.</i>	05-CV-3287
<i>Williamson v. Purdue Pharma L.P., et al.</i>	SDNY case number pending <i>The District of Massachusetts transferred this case pursuant to 28 U.S.C. § 1404 on April 7, 2004. The case number in District of Massachusetts was 1:04-CV-10154.</i>

Attachment A to Order No. 1 includes one case that does not contain antitrust allegations against Purdue, *Purdue v. Boehringer Ingelheim, GmbH*, Civ. No. 99-3658, and thus may not be related to the *In re OxyContin Antitrust Litigation* matter.

One additional case, *Coker v. Purdue Pharma Co.*, No. CT-0000121-04, with different but related allegations against Purdue, was brought in Tennessee state court. Purdue removed the case to the Western District of Tennessee, but the court granted remand based on the unique allegations of that complaint. *Coker v. Purdue Pharma Co.*, 314 F. Supp. 2d 777 (W.D. Tenn. 2004). The Tennessee Circuit Court subsequently granted Purdue's motion for judgment and dismissed the case. *Coker v. Purdue Pharma Co.*, No. CT-0000121-04, 2005 WL 2428434 (Tenn. Cir. Ct. Sept. 27, 2005). The plaintiff has appealed the dismissal.

IV. Additional Suggested Issues for Case Management Conference

- A. Consideration of Purdue's proposal that the antitrust cases, including discovery and any motions, be held in abeyance pending a ruling on the petition for rehearing and *en banc* review of the Federal Circuit's decision in the Endo Patent Actions. *See, e.g.*, Notice Regarding Federal Circuit Proceedings, dated June 7, 2005; Purdue's Motion to Stay Proceedings Pending Resolution of Patent Appeal, dated August 25, 2004, submitted in *Balloveras v. Purdue Pharma*, Case No. 04-CV-4039; Letters from Timothy C. Hester to Judge Stein, dated July 1, 2004, August 19, 2004, and September 23, 2004.

V. List of Affiliated Companies

The following list provides the Purdue Defendants, as well as all companies affiliated with the Purdue Defendants, that would be disclosed pursuant to Federal Rule of Civil Procedure 7.1.

- A. The Purdue Pharma Company.²
- B. Purdue Pharma L.P.
- C. The Purdue Frederick Company
- D. Purdue Pharmaceuticals L.P.
- E. The P.F. Laboratories, Inc.
- F. Purdue Pharma Inc.
- G. Euro-Celtique S.A.
- H. Pharmaceutical Research Associates, Inc.

² As of September 30, 2004, Purdue Pharma L.P. is the successor-in-interest to The Purdue Pharma Company.

VI. List of Associated Counsel

The following list includes Purdue's antitrust counsel in the *In re OxyContin Antitrust Litigation*. It also includes Purdue's patent counsel in the *Endo*, *Impax*, *Boehringer Ingelheim*, and *Teva* matters. Local counsel who participated in the individual antitrust cases previously pending outside of the S.D.N.Y. are not included because Purdue does not anticipate that they will take part in proceedings in this Court.

A. Antitrust Counsel

Timothy C. Hester
Mark H. Lynch
Christopher N. Sipes
Paul W. Schmidt
Thomas J. Cosgrove
Jason M. Knott*
Jenny R. Silverman*
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2401
Tel: (202) 662-6000

C. William Phillips
Michael C. Nicholson
COVINGTON & BURLING
1330 Avenue of the Americas
New York, New York 10019-5400
Tel: (212) 841-1000

B. Patent Counsel

Herbert F. Schwartz
Robert J. Goldman
Denise L. Loring
Duane-David Hough
Richard A. Inz
Pablo D. Hendler
ROPES & GRAY LLP
1251 Avenue of the Americas
New York, New York 10020
Tel: (212) 596-9000
Counsel in Purdue v. Endo, Purdue v. Boehringer Ingelheim, Purdue v. Impax

*Jason M. Knott and Jenny R. Silverman will submit a motion for *pro hac vice* admission immediately upon receipt of the certificates of good standing required by Local Rule 1.3.

John J. Normile
Thomas G. Rowan
F. Dominic Cerrito
JONES DAY
222 East 41st Street
New York, New York 10017
Tel: (212) 326-3939
Counsel in Purdue v. Teva

Respectfully submitted,

C. William Phillips (CP 3300)
Michael C. Nicholson (MN 3331)
COVINGTON & BURLING
1330 Avenue of the Americas
New York, NY 10019
(212) 841-1000
(646) 441-9031 (facsimile)

/s/ Timothy C. Hester
Timothy C. Hester (TH 0676)
Mark H. Lynch (ML 8703)
Christopher N. Sipes (CS 0294)
Paul W. Schmidt (PS 1535)
COVINGTON & BURLING
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
(202) 662-6000
(202) 662-6291 (facsimile)

December 27, 2005

Counsel for Purdue Defendants

CERTIFICATE OF SERVICE

I hereby certify that I caused true and correct copies of the foregoing PURDUE'S STATEMENT OF COUNSEL, dated December 27, 2005, to be served via U.S. mail, first class, postage prepaid, upon the following counsel of record in the within action 04-MDL-1603 (SHS), at their last known addresses in accordance with Rule 5 of the Federal Rules of Civil Procedure on the 27th day of December, 2005:

Brad Allen Antonacci, Esq.
Suite 1015
321 West State Street
Rockford, IL 61105

David Boies, Esq.
Boies, Schiller & Flexner, LLP
10 North Pearl Street
Albany, NY 12207

James V. Bashian, Esq.
Law Offices of James V. Bashian, P.C.
Fairfield Commons
271 Route 46 West
Fairfield, NJ 07004

John M. Broderick, Esq.
Pugh, Jones & Johnson, P.C.
Suite 3400
180 North LaSalle Street
Chicago, IL 60601

Matthew J. Becker, Esq.
Day, Berry & Howard
CityPlace I
Hartford, CT 06103

Joseph M. Burns, Esq.
Suite 1720
122 South Michigan Avenue
Chicago, IL 60603-2002

Franklin K. Belhasen, II, Esq.
Belhausen Law Office
P.O. Box 670
201 Mill Branch Road
Paintsville, KY 41240

Patrick Edward Cafferty, Esq.
Miller, Faucher, Cafferty & Wexler, LLP
Suite 3200
30 North LaSalle Street
Chicago, IL 60602

Jeffrey A. Berens, Esq.
Dyer and Shuman
801 East 17th Avenue
Denver, CO 80218-1417

Kathleen Currie Chavez, Esq.
Chavez Law Firm
P.O. Box 772
Geneva, IL 60134

Donald L. Bilgore, Esq.
Bilgore, Reich, Levine & Kantor
Suite 950
16 East Main Street
Rochester, NY 14614

Brian D. Coggio, Esq.
John E. Lavelle, Esq.
38 Willis Avenue
Mineola, NY 11501

Eric L. Cramer, Esq.
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103

Daniel F. Dansford, Esq.
250 West Main Street
2300 Lexington Financial Center
Lexington, KY 40507

Timothy E. DeMasi, Esq.
Pennie & Edmonds, LLP
1155 Avenue of the Americas
New York, NY 10036

Aashish Desai, Esq.
Mower Carreon & Desai
Suite 360
2301 Dupont Drive
Irvine, CA 92612-7503

Michael Dore, Esq.
Lowenstein Sandler, PC
65 Livingston Avenue
Roseland, NJ 07068

Angela K. Drake, Esq.
Lowther, Johnson Attorneys at Law
20th Floor
901 St. Louis Street
Springfield, MO 65806

Richard B. Drubel, Esq.
Boies, Schiller & Flexner
26 South Main Street
Hanover, NH 03755

Robert J. Dyer, Esq.
Dyer Donnelly
801 E. 17th Avenue
Denver, CO 80218-1417

John Famularo, Esq.
250 West Main Street
2300 Lexington Financial Center
Lexington, KY 40507

David T. Fischer, Esq.
Porter, Wright, Morris & Arthur, LLP
Suite 500
1919 Pennsylvania Avenue, NW
Washington, DC 20006

Robert M. Foote, Esq.
Foote, Meyers, Mielke, Flowers &
Solano
416 South Second Street
Geneva, IL 60134

Robert J. Goldman, Esq.
Fish & Neave
1251 Avenue of the Americas
New York, NY 10020

Stefan C. Grant, Esq.
Kenyon & Kenyon
One Broadway
New York, NY 10004-1050

Steven J. Gutter, Esq.
Kahn & Gutter
Paine Webber Plaza / Penthouse 4
8211 W. Broward Boulevard
Plantation, FL 33324

M. King Hill, III, Esq.
Venable LLP
Suite 1800
Two Hopkins Plaza
Baltimore, MD 21201

Duane-David Hough, Esq.
Fish & Neave
875 Third Avenue
New York, NY 10022-6250

James D. Johnson, Esq.
P.O. Box 1546
Plaintsville, KY 41240

Walter Jones, Jr., Esq.
Pugh, Jones & Johnson, P.C.
Suite 2910
180 N. LaSalle Street
Chicago, IL 60601

Allyn Zissel Lite, Esq.
Lite, Depalma, Greenberg & Rivas LLC
Two Gateway Center
Newark, NJ 07102-5003

Mark J. McClenathan, Esq.
Suite 1015
321 West State Street
Rockford, IL 61105

James E. Miller, Esq.
Scott & Scott, LLC
108 Norwich Avenue
P.O. Box 192
Colchester, CT 06415

Donna Siegel Moffa, Esq.
Trujillo, Rodriquez & Richards, LLP
8 Kings Highway West
Haddonfield, NJ 08033

John E. Nathan, Esq.
Fish & Neave
1251 Avenue of the Americas
New York, NY 10020

John J. Normile, Esq.
Jones Day
222 East 41st Street
New York, NY 10017-6702

Mary K. Periolat, Esq.
Pugh, Jones & Johnson, PC
Suite 3400
180 North LaSalle Street
Chicago, IL 60601

Susan J. Pope, Esq.
Frost Brown Todd, LLC
250 West Main Street
2700 Lexington Financial Center
Lexington, KY 40507

Robert T. Rhoad, Esq.
Porter, Wright, Morris & Arthur, LLP
Suite 500
1919 Pennsylvania Avenue, NW
Washington, DC 20006

Jill Irene Rogers-Manning, Esq.
Suite 1015
321 West State Street
Rockford, IL 61105

Kimberly Horton Schultz, Esq.
Boies, Schiller & Flexner LLP
26 South Main Street
Hanover, NH 03755

Susan R. Schwaiger, Esq.
Cohen, Milstein, Hausfeld & Toll,
PLLC
150 East 52nd Street
New York, NY 10022

Kip B. Shuman, Esq.
Dyer and Shuman
801 East 17th Avenue
Denver, CO 80218-1417

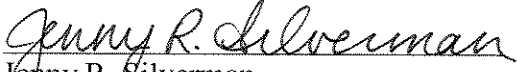
David F. Sorensen, Esq.
Berger & Montague, PC
1622 Locust Street
Philadelphia, PA 19103

Jennifer W. Sprengel, Esq.
Miller, Faucher and Cafferty, LLP
30 North LaSalle Street
Chicago, IL 60602

Kathleen M. Stockwell, Esq.
Suite 1015
321 West State Street
Rockford, IL 61105

Dianne M. Nast, Esq.
RodaNast, P.C.
801 Estelle Drive
Lancaster, PA 17601

Dated: December 27, 2005


Jenny R. Silverman
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2401
(202) 662-6000